

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

DATE MAILED: 10/16/2006

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/774,358	02/05/2004	William Stern	P/546-279 REISSUE	8408	
2352	7590 10/16/2006		EXAMINER		
,	K FABER GERB & S	HAGHIGHATIAN, MINA			
1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403		S	ART UNIT	PAPER NUMBER	
,			1616		

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary

Application No.	Applicant(s)		
10/774,358	STERN, WILLIAM		
Examiner	Art Unit		
Mina Haghighatian	1616		

All participants (applicant, applicant's representative, PTO personnel):						
(1) Mina Haghighatian.	(3) <i>Mark Farley</i> .					
(2) William Gray.	(4)	·				
Date of Interview: <u>05 October 2006</u> .						
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant	2)□ applicant's representative	e)				
Exhibit shown or demonstration conducted: d) Yes If Yes, brief description:	e)⊠ No.					
Claim(s) discussed: All.						
Identification of prior art discussed: <u>All</u> .						
Agreement with respect to the claims f) was reached.	g)⊠ was not reached. h)□ N	I/A.				
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: <u>See Continuation Sheet</u> .						
(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)						
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.						

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: This interview was conducted after Amendments and Remarks were filed by Applicants. Applicants and Examiner discussed the rejections made on the non-final Office Action and the Amendemnts and Remarks. Mr. Grey started by inquiering about the new matter rejections. Examiner explained that Table 1 in column 5 of parent specification (original patent) only recite citric acid and that the 10 to 25 mM range claimed has no support since the claims recite citric acid, citric acid salt and a combination thereof. Mr. Grey said that they may concider filing a Declaration in support of Table 1. It was also explained that the term "aggregate concentration of all such bioavailability enhancing agents" is still deemed new matter and that Applicant's arguments are not persuasive. Applicant stated they may reconcider the said language to overcome the rejection. With regard to the range of 250 to 350 mOsm/liter, Examiner mentioned that since the said term was originally presented in the parent Application and the provisonal Application this is not a new matter rejection. Examiner, however suggested the range be inserted in the present specification. The prior arts of record were discussed with reference to the rejections. It was agreed that if the new matter rejections are overcome and in light of Applicant's arguments Kagatani and Dua references may fall. Grebow reference is still deemed an apropriate reference since it teaches the nasal formulation and administration of calcitonin and citric acid/citrate. It is taught that citric acid/citrate is added for controlling pH and increasing stability of the formulation. Applicant argued that the ranges taught by Grebow are broader than the ranges stated in the instant claims. Specifically, the range of citrate is from 10 to 500 mM compared to smaller range of 10 to 25 or 50 mM stated in the instant claims. The suitable pH is from 3.0 to 8.0 compared to 3.5 to 3.9 in the instant claims. The exmainer also mentiond that one or more of the references discussed in the litigation documents (filed by Applicant on 09/28/06) may apply to the instant claims and may be used in the next Office Action.